Methodological Considerations in Using PROs, PROMs and PRO-PMs in ESRD

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I. Executive Summary

Patient reported measures (PRMs), including patient-reported outcomes (PROs), play a critical role in dialysis care, as one of two primary sources of information about clinical outcomes of patients. The usage of PRMs and PROs is extensive in dialysis clinics. While there are excellent PRMs to choose from, and their implementation as part of quality improvement and performance monitoring is extensive, there are still challenges to be addressed. In this paper, we summarize the literature on PRMs and their use in dialysis and in medicine generally, and we offer recommendations for improving their use in dialysis related to *Selection of PRMs*, *Mode of Administration*, and *Support for PRM Use*:

- Continue the use of KDQOL-36 for dialysis centers' internal quality improvement activities and the ICH-CAHPS for public dialysis center performance monitoring, but promote efforts to modify these instruments by incorporating PROMIS general health items (KDQOL-36) and reducing the length of the ICH-CAHPS.
- Adopt a PRM of whether dialysis patients have been informed about their option for transplant.
- Evaluate equivalence between electronic and paper versions of PRMs prior to widespread use of electronic administration.
- Explore reimbursement of costs of PRM administration by the Centers for Medicare and Medicaid Services.
- Continue development of provider trainings in PRM administration and interpretation.

These recommendations will help dialysis care decision-makers, clinicians, and applied researchers take the next steps toward enhancing PRM use in dialysis.

II. Intro and Definitions

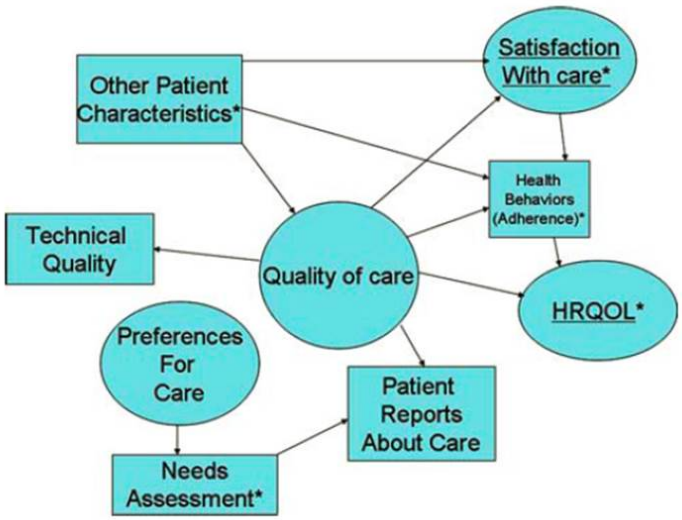
Patient reported measures (PRMs), including patient-reported outcomes (PROs), play a critical role in medical care, as one of two primary sources of information about clinical outcomes of patients.[1] The other source of information is "non-patient-reported" biologically-based patient data (e.g., laboratory values such as hemoglobin level, calcium, phosphorus, parathyroid hormone albumin, and hemoglobin). PRM assessment may be included at several stages of the patient-provider clinical encounter such as during the time when the health issue is elicited, when the course of treatment or action is discussed, when the treatment plan is created, during the course of treatment itself, and after the treatment is concluded.[1] PRMs are rarely included in clinical registries or incorporated into clinical decision-making,[1] but they are widely-used in clinical trials of new medications[2] and other medical treatments or health interventions.[3] For instance, PROs have become instrumental in the field of oncology, as many chemotherapy drugs can successfully destroy cancer cells, but the subsequent impact on the patient's health-related quality of life (HRQOL) may differ substantially.[4] Therefore, in addition to measures of clinical performance, such as patient survival, HRQOL is often an important secondary outcome in comparisons of drugs' effectiveness.[5,6]

The National Quality Forum (NQF) has adapted the FDA definition of a PRO, which is: ''any report coming from patients about a health condition and its treatment, without interpretation of the patient's response by a clinician or anyone else'' (p. 2).[2] The NQF makes the further distinctions of patient-reported outcome measures (PROMs), defined as an, "Instrument, scale, or single-item measure used to assess the PRO concept as perceived by the patient, obtained by directly asking the patient to self-report," and PRO-based performance measures (PRO-PMs), defined as, "a performance measure that is based on PROM data

aggregated for an accountable healthcare entity." The broad scope of the FDA's definition of PROs is consistent with what others have referred to as PRMs.[1] In theoretical frameworks such as Andersen's Behavioral Model of Access to Health Care,[7] outcomes have a more limited scope, including only the patient's health status (perceived or evaluated) and satisfaction with care. On the other hand, important factors that may be patient-reported, such as health behaviors, attitudes toward health, and patients' experiences with health care are not themselves outcomes, and therefore do not fall under PROs.

Fung and Hays offered a framework that articulates the relationships between types of PRMs, including PROs.[1] (Figure 1) At its most basic level, this framework distinguishes between the underlying concepts to be measured (circles) and direct indicators that do not represent an underlying concept (boxes). Both direct indicators and underlying concepts can be measured with PRMs. For example, a health behavior such as adherence to medications can be measured by patient reports on whether they have or have not adhered to a prescribed medication regimen in response to questions asking directly about medication taking (e.g., "Did you take your medications yesterday at the prescribed times?"); such questions assess whether the behavior occurred or not, and they do not intend to represent a larger, underlying concept. On the other

Figure 1. Fung and Hays Measurement Framework



Originally published in Fung CH, Hays RD. Prospects and challenges in using patient-reported outcomes in clinical practice. *Qual Life Res.* 2008; 17(10):1297-1302.

hand, HRQOL is a concept that cannot be indicated directly and usually requires a series of questions that each represent related aspects of the larger concept.

Major concepts in this framework include preferences for care, HRQOL, quality of care, and satisfaction with care. The direct indicators include patient characteristics, technical quality of care, needs assessment, patient reports about care, and health behaviors. Of the many relationships between these constructs and indicators, it is important to note that HRQOL is exclusively an outcome and itself does not influence the other depicted constructs or indicators. On the other hand, HRQOL is influenced by other concepts and indicators, including health behaviors and quality of care, which do not count as outcomes, and therefore are not PROs. Though satisfaction with care is generally considered a PRO, it also impacts health behaviors. It is important to distinguish between patients' *satisfaction with care*, and patients' *experiences with care. Satisfaction with care* regards discrepancies between patients' expectations for care and the care they actually receive.[8] *Experience with care* refers to objective dimensions of the care patients receive and interactions with different elements of the health care system.[8] Indicators like patient reports about care may be used to measure their experiences with care, along with their preferences for care and ratings of quality of care. Of these, the needs assessment and patient reports about care would be distinguished as PRMs, while technical quality of care would not. Additionally, other patient characteristics, like demographics, are also considered PRMs.

Table 1. provides each of the underlying concepts and direct indicators that Fung and Hays count as PRMs, and gives examples of PRMs used to capture each. For HRQOL, the PROMIS-29 instrument is a generic multi-dimensional measure that can elicit patient reports of HRQOL. (Detailed in Section III below). Similarly, satisfaction with care can be assessed using

the Functional Assessment of Chronic Illness Therapy Treatment Satisfaction (FACIT TS) instrument. The Clinician & Group CAHPS represents an example of a patient report about care. Questions about whether and how often patients use tobacco are examples of health behaviors, which are typically measured directly.

Table 1. Underlying Concepts and Direct Indicators with Example Patient-Reported Measures	
Concept/Indicator	**Example of PRM**
Health-Related Quality of Life	PROMIS[a]-29[9]
Satisfaction with Care	FACIT[b] Treatment Satisfaction[10]
Patient Reports about Care	Clinician & Group CAHPS[c,11]
Needs Assessment	Control Preferences Scale[12]
Patient Demographic Characteristics	Age, gender, race/ethnicity, education attainment
Health Behaviors	Tobacco Use (e.g., yes vs. no, frequency of use)
[a]Patient Reported Outcomes Measurement Information System; [b]Functional Assessment of Chronic Illness Therapy; [c]Consumer Assessment of Health Care Providers and Systems	

In the field of dialysis, PRMs are used as performance measures, or PRO-PMs. Since the Centers for Medicare and Medicaid Services (CMS) covers the cost of patient care for most renal replacement therapy, an extensive effort has been made to track patient experiences with care and HRQOL, with large data collection projects funded by government agencies. If dialysis centers have not demonstrated that the mandated PRM assessment has occurred, their reimbursement from CMS is in jeopardy.

Using the Fung and Hays framework as a starting point, this report will identify key PRMs relevant to dialysis patients, and then review key methodological issues around the use of these measures. We focus on how PRMs are used in research and clinical settings, which measures are available for use with dialysis patients, and provide recommendations for overcoming challenges in administering PRMs. Within this discussion, we will also comment on how current PRMs may be used for performance measurements (PRO-PMs). The anticipated

audiences for this report are dialysis medical providers and applied researchers who seek to use PRMs with dialysis patients, as well as dialysis care regulators (e.g., CMS), payors (insurance companies), and policy makers.

III. Why, When, and How PRMs are Used in Research and Clinical Settings

PRMs offer many potential benefits. Perhaps most importantly, they provide information about aspects of health that are important to patients and that are best, or that can only be, obtained from patients directly.[13] A patient's health status can be measured by providers without patient input. However, provider reports in this case are more unreliable and less valid than patient reports.[14] PRMs operate on the philosophy that patients are the best source of information about their own health experiences and perspectives. Therefore, in addition to key non-patient reported indictors of health, PRMs play an important role in evaluating a patient's health. PRMs also provide an opportunity for patients to report on their experiences with health care providers and health services, which is associated with how likely patients are to use those services again and contributes to comparative information about the quality of care.[13,15]

Given the importance of PRMs to understanding patients' health and experiences with health care, it is often advantageous to include them in health care interventions. The International Society for Quality of Life Research (ISOQOL) put forth guidance for incorporation of PROs in clinical care.[16,17] In doing so, they use Greenhalgh and colleagues' taxonomy, which makes the following recommendations for implementing PRMs in clinic.[18]

- First, PRMs are used to screen for health problems.
- Once health problems are identified, PRMs are used to monitor those problems over time.

- Finally, clinicians need PRM information to facilitate shared decision-making about treatment.

This framework helps identify which patients might benefit most from interventions to improve health, or to signal which interventions are most appropriate or effective. For example, reports of physical functioning will help determine whether interventions that include increased physical activity are likely to be effective.[1,13] Additionally, PRMs can be used to elucidate problems with the care experience and environment, which can enhance understanding of the most appropriate interventions for specific subgroups of patients.[13] Regarding dialysis specifically, patients with renal failure must obtain renal replacement therapy, but have several options about how to treat this condition, including several different types of dialysis, as well a pursuit of transplant from a deceased or living donor, or no treatment at all.

The Consolidated Standards of Reporting Trials (CONSORT) statement addresses inclusion of PROs.[19] For example:

- Scoggins and Patrick examined the use of PROs in *ClinicalTrials.gov* randomized controlled trials (RCTs) between 2004-2007[20]. From 17,704 registered RCTs, 14% (n=2,481) reported using a PRO, but only 41% of these identified the instrument used.

However, the literature on the impact of PROs incorporated into interventions has been mixed.

- A recent report from a RCT with 766 cancer patients on chemotherapy who were assigned either usual care or to a symptom-reporting and management intervention wherein nurses were alerted of patient-reported worsening symptoms electronically found that those receiving the intervention had significantly fewer visits to the emergency room and better survival at 1 and 5 years after enrollment in the study.[21,22]

- Valderas and colleagues conducted a review of 28 studies that tested the impact of administering PRMs in clinical settings on improvements in processes of care (e.g., facilitating patient education, increasing referrals), outcomes of care (e.g., improving functional status), and physician satisfaction with care (e.g., physician-rated usefulness of new information provided).[13] The proportion of interventions with a significant, positive impact varied by the type of outcome, but occurred in 40-50% of the studies, showing promise for PROs to improve care.

Despite the potential benefit of administering PRMs in clinic, their uptake and incorporation in clinical care has been slower than desired. Literature on barriers to implementing PRMs,[1,13] in dialysis[23] and in other clinical settings,[24,25] have identified the following types of barriers: insufficient provider time, training and education to administer PRMs; skepticism about the reliability, validity, or responsiveness of PRMs; burden on patients to complete the measures; high financial costs associated with routine PRM administration; and insufficient motivation to use the measures among providers. Relatedly, Fung and Hays point to multiple studies showing that physicians do not change their treatment plans when provided with data from HRQOL instruments,[1] calling into question whether providers judge the data resulting from PRMs to be useful.

The field of dialysis represents one area where PRMs have been well-integrated into clinical interventions with patients, and they are used as PRO-PMs. In their Conditions for Coverage (42 CFR §494.90), CMS mandated that each dialysis patient's physical and mental health must be monitored, and this often occurs with the use of a standardized HRQOL measure.[26] The patient reports of HRQOL are then used to create individually-tailored interventions that focus on the areas where the patient's HRQOL needs most improvement. In addition, reports of patient

experience with care using the CAHPS® In-Center Hemodialysis survey is included in the Quality Incentive Program (QIP) evaluation metrics for dialysis centers.[27]

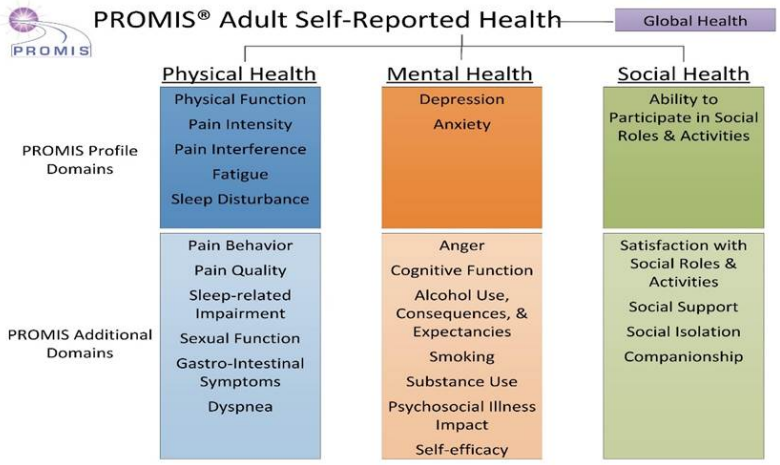
IV. Types of PRMs

PROs

PROMIS®

The most frequently assessed PRO is HRQOL. Over the past decade, the NIH PROMIS® project produced the state-of-the-science of HRQOL measures. PROMIS took an innovative approach to the development and evaluation of PROs by use of item response theory (IRT) and computer adaptive testing (CAT), drawing from large banks of items to generate efficient, reliable, and parsimonious individually-tailored measures of HRQOL.[9] Figure 2 shows the PROMIS conceptual model that features Global Health, Physical Health, Mental Health, Social Health, and several domains within these areas.

Figure 2. PROMIS Conceptual Model for Health-Related Quality of Life



Published on PROMIS. 2016; http://www.healthmeasures.net/explore-measurement-systems/promis. Accessed December 26th, 2016.

The PROMIS project brought together a national brain trust of multiple content area experts, methodological experts, clinicians from academia, and NIH project officers. Large scale field testing was conducted with internet survey panels and patients from 6 primary study sites to represent the general population and those with chronic conditions such as heart disease, cancer, rheumatoid arthritis, osteoarthritis, psychiatric illnesses, chronic obstructive pulmonary disease, spinal cord injury, and kidney disease.[9,28]

The PROMIS measures can be assessed as static "short forms" or through CAT using a range of data capture and scoring platforms, including Assessment Center (http://www.assessmentcenter.net/). Both forms of administration have demonstrated exceptional psychometric properties.[9,29,30] The PROMIS measures use a T-score metric, which has a mean of 50 and standard deviation of 10, with the mean referenced to the U.S. general population. Using this metric, different subgroups and individual patients can be compared to the general population or other referent groups.

There are many PROMIS measures, for both adult and pediatric populations. The PROMIS-29 is analogous to the SF-36, with physical and mental health summary scores components arising out of 8 domains: 1) physical function; 2) anxiety; 3) depression; 4) fatigue; 5) sleep disturbance; 6) ability to participate in social roles and activities; 7) pain interference; 8) pain intensity. In addition, a range of domain-specific measures are available in physical health (e.g., physical function, sexual function), mental health (e.g., cognitive function, anger), and social health (e.g., ability to participate in social roles, companionship, social isolation).

The PROMIS measures are *generic*. The measures are designed to be equally applicable to a variety of chronic conditions, patients of all races, and patients of all age groups (separate instruments for adult and pediatrics). For this reason, PROMIS measures may be well-suited to capture the global aspects of HRQOL for dialysis, but may not fully reflect the specific issues facing dialysis patients. Though there is increasing attention paid to the potential for PROMIS measures for use in kidney disease,[31,32] the PROMIS measures have not been systematically used with adult dialysis patients. However, the PROMIS pediatric measures have begun to be implemented with pediatric ESRD patients.[33,34]

Kidney Disease Quality of Life (KDQOL) Measures

Targeted measures, in contrast, are designed to be relevant to a particular subgroup. The relative advantages and disadvantages of generic versus targeted HRQOL measures have been discussed.[35] Generic measures in theory can be administered to anyone and compared across different subgroups. Targeted measures are putatively more applicable and sensitive to the group being targeted. When possible, it is recommended that a combination of generic HRQOL measures be used. For example, the original KDQOL short-form (KDQOL-SF) includes the SF-36 as its generic core, supplemented by 11 kidney disease targeted domains: Symptoms/Problems of Kidney disease (34 items), Effects of Kidney Disease (20 items), Burden of Kidney Disease (4 items), Work Status (4 items), Cognitive Function (6 items), Quality of Social Interactions (4 items), Sexual Function (4 items), Sleep (9 items), Social Support (4 items), Dialysis Staff Encouragement (6 items), and Patient Satisfaction (2 items).

The original psychometric analyses of the KDQOL-SF showed that these targeted scales had acceptable to excellent internal consistency reliabilities,[36] ranging from 0.76 (Sleep) to 0.94 (Effects of Kidney Disease). A factor analysis revealed that these 11 scales and the SF-36 scales loaded substantially on 4 factors representing physical health, mental health, kidney disease-targeted health, and patient satisfaction. Construct validity was evidenced through significant associations with patient-reported good days, patient-reported bad days, self-rating of quality of life compared to those without kidney disease, ability to do everything the patient wants to do, number of disability days in the last 30 days, and overall rating of health.

The KDQOL-36 includes the SF-12 as the generic core and 24 additional items targeted at kidney disease (Symptoms/Problems, Effects of Kidney Disease, and Burden of Kidney Disease). The Symptoms/Problems scale includes 12 potential symptoms kidney patients may face (e.g., chest pain, dry and itchy skin, nausea). Patients are asked to rate how bothered they

are by each symptom from “Not at all bothered” to “Extremely bothered”, then a Symptoms/ Problems scale score is created by calculating the mean of these responses (ranging from 1-5, with higher scores indicating lower symptom burden). The Effects of Kidney Disease scale contains 8 items and examines the practical impacts of kidney disease on the patient’s activities (e.g., diet and travel), independence (e.g., dependence upon doctors), and self-concept (e.g., personal appearance). The response options and scoring for this scale are the same as that of the “Symptoms/Problems” scale, and higher scores are interpreted as lower negative effect from kidney disease. Finally, the Burden of Kidney Disease scale contains 4 items representing potential ways kidney disease may have an overall burden on their life (e.g., “My kidney disease interferes too much with my life”) and asks patients to rate each from “Definitely true” to “Definitely false”. The scoring is the same as the other two KDQOL scales, and they are interpreted as higher scores indicate lower overall burden from kidney disease.

Table 2. provides details of the KDQOL scales and several other HRQOL instruments used in dialysis. One generic HRQOL measure, the SF-36, is featured due to its frequent application among dialysis patients, as well as its use as the generic HRQOL measures included in the KDQOL-SF. The remaining scales are kidney or dialysis-targeted. For each scale, advantages and disadvantages to use in dialysis are specified. Important advantages of the measures include patient involvement in measure development, comprehensive coverage of domains and symptoms relevant to kidney patients, good psychometric properties, and sufficient brevity to reduce administrator (provider) and respondent (patient) burden. Disadvantages largely comprise the absence of these characteristics.

Table 2. Advantages and Disadvantages of HRQOL Measures for Dialysis Patients		
Measure	**Advantages**	**Disadvantages**
SF-36[37,38]	• Developed with patient input • Multi-dimensional HRQOL scale with physical or mental health component scores and 8 domain subscales • Evidence of reliability and validity	• No kidney-targeted items or scales • May be too long for all applications
Kidney Disease Quality of Life-Short Form (KDQOL-SF)[36,39]	• Developed with patient input • Contains generic and targeted HRQOL scales • Multi-dimensional set of scales with 11 kidney disease subscales representing many HRQOL domains • Evidence of reliability and validity	• Full instrument may be too long for all applications
KDQOL-36[40]	• Brief • Evidence of reliability and validity	• Less comprehensive coverage of HRQOL domains than KDQOL-SF
100-Category Checklist[41]	• Comprehensive coverage of symptoms and problems associated with kidney disease • Evidence of reliability and validity	• More focus on functioning and symptoms over wellbeing • Not developed with patient input
Short Version Checklist[42]	• Brief • Evidence of reliability and validity • More patient input to item selection compared to 100-Category Checklist	• More focus on functioning and symptoms over wellbeing
CHOICE Health Experience Questionnaire (CHEQ)[43]	• Developed with patient input • Contains 21 kidney disease targeted domains • Evidence of reliability and validity	• May be too long for all applications • Rigorous approach to assessment of dimensional structure not taken
Dialysis Symptom Index (DSI)[44]	• Patient-generated, comprehensive list of symptoms associated with dialysis • Evidence of reliability and validity	• Focused on symptoms only
ESRD-SCL[a,45]	• Multi-dimensional symptom scale • Evidence of reliability and validity	• Not developed with patient input • Focused on symptoms only • May be too long for all applications
Ferrans & Powers Quality of Life Index[46]	• Multi-dimensional HRQOL scale representing 4 domains with dialysis-targeted items • Evidence of reliability and validity	• Not all items and domains health-related • May be too long for all applications
Hemodialysis Quality of Life Questionnaire[47]	• Multi-dimensional HRQOL scale with dialysis-targeted items • Items generated with patient input • Evidence of reliability and validity	• May be too long for all applications
Kidney Disease Questionnaire[48]	• Developed with patient input • Multidimensional profile measure (5 total scales) covering physical, mental, and social health • Evidence of reliability and validity	• No generic HRQOL items included, potentially limiting comparability among patient populations
Physical Symptom Distress Scale[49]	• Evidence of reliability and validity • Brief	• Not developed with patient input • Focused on physical symptoms only
[a]End-Stage Renal Disease Symptom Checklist – Transplant Module		

Considering the advantages and disadvantages of the HRQOL measures considered in Table 2., we recommend the continued use of the KDQOL-36 instrument with dialysis patients for the purposes of dialysis centers' internal quality improvement. The KDQOL-36 has attractive psychometric properties, and it has been successfully applied to date with many thousands of dialysis patients, providing an unrivaled opportunity to compare individual patient scores to norms from the general dialysis population or from subgroups within this population. Despite these properties, we do not recommend, at this time, that HRQOL be used by CMS for dialysis quality assessment, including KDQOL-36 scores. This issue has been debated in the literature[50,51], but further research on the potential ramifications of using any HRQOL measure to rate dialysis center performance should be conducted before this strategy is pursued.

There are opportunities to improve the KDQOL-36. The incorporation of the SF-12 as the KDQOL-36's generic HRQOL companion is no longer ideal. As described in the *PROMIS* subsection above, there have been major advancements in HRQOL measurement science, and the PROMIS measures now represent the state-of-the-science in generic HRQOL measures. Additionally, while the KDQOL-36 subscales have represented important dimensions of HRQOL for dialysis patients, they were developed over 20 years ago, and a changing dialysis population could signal the need for an update, or at least re-assessment, of these kidney-targeted scales. **Therefore, we recommend that a new version of the KDQOL-36 be developed with PROMIS measures as a generic core, and exploration of potential for fine-tuning among the kidney disease-targeted scales**. An important caveat to this recommendation is that an approach should be taken such that new scores yielded from an updated version of the KDQOL-36 should be statistically linked to the original version. Over and above its incorporation into a newer version of the KDQOL-36, we do not recommend additional use of the PROMIS

measures for mandated quality improvement or outcomes monitoring in dialysis centers. However, specific uses of any of the PROMIS measures, like research projects in which PROMIS-relevant domains are involved, are strongly recommended.

Other Types of PRMs

In addition to the PROs described in the previous section, there are many other types of PRMs that play a critical role in understanding patients' health and health care experiences in dialysis. Considering Fung and Hays's framework (Figure 1), other types of PRMs that need to be considered include patients' health behaviors, preferences for care, patients' experiences with care, and even patients' decision-making characteristics about how they treat their kidney disease. There are multiple PRMs that fit these categories in use in research and in clinical practice, though there is significant opportunity to expand their use.

CAHPS In-Center Hemodialysis Survey

The CAHPS In-Center Hemodialysis Survey was supported by the Agency for Health Research and Quality and CMS.[52] CAHPS surveys are based on a definition of patient experience as "the range of interactions that patients have with the health care system, including their care from health plans, and from doctors, nurses, and staff in hospitals, physician practices, and other health care facilities".[52] CMS has adopted several CAHPS measures for quality improvement in addition to ICH-CAHPS, including the CAHPS Hospital, Home and Community-Based Services, Hospice, Surgery, and Medicare ambulatory surveys. [53] The ICH-CAHPS survey items are targeted at care provided to hemodialysis patients, and these items would not be appropriate for consumers of other types of health services.

The ICH-CAHPS includes 3 composites, including Nephrologists Communication and Caring (6 items; e.g., "In the last 3 months, how often did your kidney doctors explain things in a

way that was easy for you to understand?"), Providing Information to Patients (9 items; "Did dialysis center staff at this center ever review your rights as a patient with you?"), and Quality of Dialysis Center Care and Operations (17 items; "In the last 3 months, how often did the dialysis center staff show respect for what you had to say?"). Additionally, 3 other items provide global ratings of patients' experience with their kidney doctors, dialysis center staff, and dialysis center. Most ICH-CAHPs items (but not all) have a range of four response options from "Never" to "Always" or a range of two options, including "Yes" and "No". For each composite, scores are created by determining the proportion of answers to each response option for all questions in the composite, then averaging the proportion of those responding to each answer choice in all questions; e.g., "Top Box" scores refer to the average proportion of the most positive responses. Item-scale correlations and internal consistency reliability estimates have provided supported for the reliability of these scales: Nephrologists Communication and Caring $\alpha = 0.89$, Quality of Dialysis Center Care and Operations $\alpha = 0.93$, and Providing Information to Patients $\alpha = 0.75$.[54]

Figure 3. ICH-CAHPS 2015 National and State Average Scores

NATIONAL AND STATE AVERAGES
FROM THE 2015 ICH CAHPS SPRING AND FALL SURVEYS

State	Survey Year	State Average Nephrologists Communication and Caring[1]			State Average Quality of Dialysis Center Care and Operations			State Average Providing Information to Patients		State Average Rating of the Nephrologist			State Average Rating of the Dialysis Center Staff			State Average Rating of the Dialysis Facility			State Average Response Rate[2]	Total Completed Surveys
		Top Box	Middle Box	Lower Box	Top Box	Middle Box	Lower Box	Top Box	Lower Box	Top Box	Middle Box	Lower Box	Top Box	Middle Box	Lower Box	Top Box	Middle Box	Lower Box		
National	2015	66	17	17	61	22	17	78	22	62	22	16	62	25	13	65	23	12	33	218,655
State	2015																			
AK	2015	69	17	14	63	24	13	82	18	65	18	17	68	23	9	74	17	9	36	229
AL	2015	66	15	19	60	20	20	78	22	61	23	16	60	25	15	63	23	14	33	4,525
AR	2015	65	17	18	60	21	19	80	20	61	23	16	59	26	15	63	24	13	35	1,910
AS	2015	32	11	57	53	20	27	64	36	26	17	57	36	43	21	40	46	14	17	41
AZ	2015	62	18	20	60	22	18	78	22	57	24	19	62	25	13	66	22	12	32	4,231
CA	2015	66	17	17	62	22	16	78	22	63	22	15	65	24	11	68	22	10	32	28,458
CO	2015	70	17	13	64	22	14	82	18	67	20	13	68	21	11	72	19	9	36	2,098
CT	2015	63	18	19	61	22	17	79	21	59	25	16	62	25	13	65	24	11	31	1,698
DC	2015	67	17	16	52	22	26	75	25	60	25	15	47	34	19	48	32	20	30	923
DE	2015	64	18	18	59	23	18	77	23	55	27	18	57	29	14	60	28	12	31	705
FL	2015	67	16	17	63	20	17	79	21	64	21	15	64	23	13	66	22	12	33	12,742
GA	2015	68	15	17	59	21	20	77	23	64	22	14	58	27	15	62	24	14	32	8,816
GU	2015	45	19	36	52	20	28	70	30	36	31	33	44	34	22	50	32	18	44	404
HI	2015	72	14	14	63	23	14	78	22	69	20	11	67	23	10	71	22	7	35	1,730
IA	2015	66	18	16	65	22	13	82	18	65	22	13	70	20	10	72	19	9	37	1,208
ID	2015	67	17	16	67	21	12	83	17	66	22	12	74	17	9	77	16	7	37	538
IL	2015	64	17	19	60	22	18	77	23	59	24	17	60	26	14	63	25	12	32	8,530
IN	2015	64	19	17	60	23	17	81	19	59	25	16	61	26	13	63	24	13	36	4,453

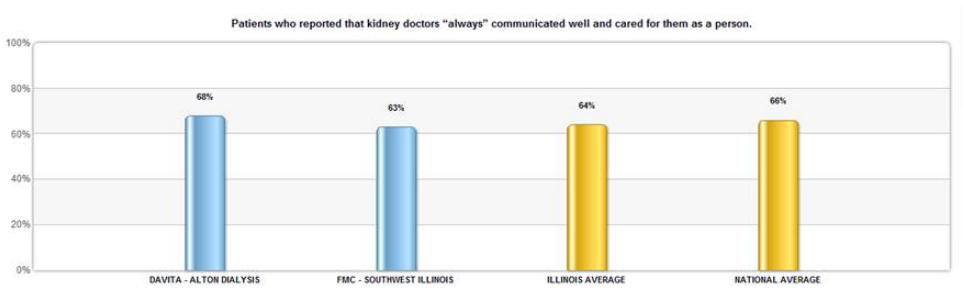
(continued)

[1] The numbers shown in the Top, Middle and Bottom Box Columns are percentages.
[2] The response rates shown are percentages.

Due to CMS's use of ICH-CAHPS as a clinical measure in the payment year (PY) 2019 QIP, it is assessed twice yearly in all dialysis centers throughout the United States. Figure 3 shows examples of national and state averages of ICH-CAHPS surveys in 2015. The results of patients'

reports about different dialysis clinics with the ICH-CAHPS are available to view on CMS's Dialysis Facility Compare website: https://www.medicare.gov/dialysisfacilitycompare/. These comparisons show differences between centers of interest, and to state and national averages. An example of comparison of two centers is given in Figure 4. Recent reports from CMS indicate that the ICH-CAHPS will continue to play a large role in dialysis service evaluation and figure into CMS's ratings of dialysis center performance.[55]

Figure 4. Example of ICH-CAHPS Items Comparisons from Dialysis Center Compare



Given its attractive measurement properties and its ability to be used for comparisons among clinics and to state and national norms, we recommend the continued use of the ICH-CAHPS for CMS's dialysis center performance monitoring. However, there are also opportunities to optimize this measure, especially to make it more parsimonious, reducing burden among patients and providers. A recent report detailed efforts to shorten the CAHPS Clinician and Group adult survey without significant reduction in reliability or clinically-important content.[56] These analyses found that Provider Communication and the Access scales could be reduced from 6 and 5 to 2 items, respectively. Noting the length of the ICH-CAHPS composites at 6 items (Nephrologists Communication and Caring), 9 items (Providing Information to Patients), and 17 items (Quality of Dialysis Center Care and Operations), the ICH-CAHPS is ripe for similar analyses.

Additional PRMs

There are several other PRMs relevant to dialysis patients. Commonly assessed health behaviors include diet and exercise regimen;[57] use of alcohol, tobacco, or other substances;[57] and adherence to medications,[58] dialysis appointments,[59] or other prescribed treatments. Similarly, preferences for care encompasses many patient preferences about use of health care like the degree of agency in their relationship and communication with providers[60] to preferences for end-of-life care.[61] Finally, and somewhat related to preferences for care, understanding the patient characteristics that influence their decision-making about their care represent important PRMs and may include readiness for particular types of treatment (e.g,, peritoneal dialysis), perceived benefits and costs of different treatments, self-efficacy to pursue different treatment options, and knowledge of treatment options.[62]

Patients' decision-making about their treatment is a particularly important domain where the use of PRMs should be expanded in clinical dialysis care. As noted above, dialysis is not the only treatment open to kidney patients, and CMS has required that patients have the opportunity to learn about their other options. According to CMS's 2008 Conditions for Coverage, dialysis centers must provide information about the option for kidney transplant to each dialysis patient, and indicate that they have done so on CMS Form-2728 at the time of initiation of chronic dialysis. In part, this requirement reflects the need to ensure that patients are able to make an informed decision, and therefore give informed consent, to their dialysis treatment. To date, this report on Form-2728 is made by the dialysis provider, but there is evidence that patients actually report being educated about transplant less-often than providers report educating them when data from Form-2728 are compared to those from patient surveys.[63] Studies like this indicate that incorporation of patient reports about whether they have received adequate education for their

treatment options, along with reports about their preferences, may be better indicators of whether informed decision-making and consent around treatment choices actually occur among dialysis patients. **Therefore, we recommend that a PRM of whether patients have been informed about their option for transplant be adopted.**

V. Administering PRMs to Dialysis Patients

There are several options for administering PRMs. As the use of PRMs in dialysis clinics has expanded, clinicians and researchers have attempted to identify the best ways to administer these measures. In 2015, ISOQOL conducted a comprehensive assessment of the resources needed and tradeoffs associated with different modes of administration of PRMs.[17] (Table 3) Each mode of administration must be considered within the context of its location, including in the clinic or in the patient's home or another personal location, where surveys can be administered by mail, phone, or on the internet (web-based). Within the clinic, surveys can be self-administered, interview-administered, or computer administered. On the phone, the concentration is on interview administration or administration through an automated, voice-activation survey system. By mail, surveys are strictly self-administered by the patient and returned by mail. Similarly, on the web, surveys are self-administered by patients. Each of these modes requires specific resources that have implications for their feasibility. For example, when surveys are administered in the clinic, a personal space is required for the survey to be completed to ensure the patient's privacy and confidentiality. Mail, telephone, and web-based surveys can overcome this need since they can be administered in the patient's home. However, successfully conducting surveys with any of these methods requires consideration of needs for staff, technology, and potentially informatics infrastructure that can be expensive.

Table 3. International Society for Quality of Life Research Summary of Mode of Administration for PRMs			
	Resources Needed	**Advantages**	**Disadvantages**
In-Clinic			
Self Admin.	• Personnel to supervise and assist • Space • Personnel for data entry	• Low-technology requirements • Implemented in any clinical setting • Relatively low cost	• Problem with low literacy patients & visual handicap • Difficult with other special populations (e.g., very young, very old) • Higher rate of missing data
Interview Admin.	• Skilled interviewer • Space • Personnel for data entry	• More personal • In-depth questioning • No issues with literacy and/or visual handicap	• Relatively expensive • Social desirability bias • Staff time
Computer Admin.	• Personnel to supervise and assist • Software to collect & report data	• Efficient data capture and entry	• Problems finding space/providing privacy • Costs to obtain & maintain PRO system • Potential software problems
Mail			
Self Admin.	• Personnel to manage mailing • Personnel for data entry	• Low-technology requirements • Potentially simpler logistics than in-clinic administration • Relatively low cost	• High non-response rate • Cannot ensure patient completes questionnaire alone • Hard to respond immediately to patient needs • Challenges scheduling assessment near clinical visit • Other limitations similar to Self-Administered In-Clinic
Telephone			
Interview Admin.	• Skilled interviewer • Personnel for data entry	• More personal • More convenient for patient • Largely circumvents literacy problem and/or visual handicap	• Lack of visual cues as compared to face-to-face • Relatively expensive • Potential problem with social desirability • Some topics may be more difficult to address
Voice Activated	• Personnel to oversee data collection • Validated interactive voice response (IVR) system	• Low cost due to automation	• May not be accepted by patients • Costs to obtain & maintain IVR system • Requires process to track and respond to any urgent problem reported by patients • Other disadvantages similar to Live Telephone Interview, plus impersonal nature
Telephone			
Web-Based	• Systems management personnel • Software to collect and report the PRO data • Training patients	• Efficient data capture with simultaneous data entry • Convenient for patient • Flexible timing for data collection	• Difficult to ensure privacy • Upfront costs for the PRO system and maintenance • Potential software problems
Reprinted from Aaronson N, Choucair A, Elliott T, et al. User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice. International Society for Quality of Life Research; 2015.			

The potential efficiencies of electronic survey administration methods have seen this approach grow in recent years. One particular benefit accrued in web-based surveys is the direct input of data into a database that can be immediately sourced for analysis. Through this approach, the need for data entry into a database is eliminated, which is attractive not only because it reduces the amount of personnel and time dedicated to administering PRMs, but also because it prevents data entry error. Once data is entered through a web interface, the ease of integrating these data within the electronic medical record is increased as well. Given that the ultimate objective of collecting PRMs is to combine them with other important clinical data, the ability to do so with ease and in real time is a considerable benefit.

One example of electronic data entry platforms for PRMs in dialysis clinics is found in the Medical Education Institute's (MEIs) administration of the KDQOL-36.[64] The MEI uses the KDQOL-36 in dialysis centers throughout the United States as part of their KDQOL-Complete program. The KDQOL-Complete programs helps meet the CMS requirement to create individualized care plans for each dialysis patient.[64] The KDQOL-Complete program assesses dialysis patients using the KDQOL-36 and tailors care plans for each patient in order to increase areas of HRQOL that are below expectations. The ability to enter data electronically into the KDQOL-Complete computerized platform allows for automated scoring of the KDQOL-36 so that individual patients' scores can be viewed immediately. Additionally, this computerized system can compare an individual patient's scores to national norms and generate illustrative graphics to help the dialysis provider and patient understand the scores.

Despite these benefits, some considerations for the integrity of electronic PRM administration should be made before pursuing this strategy. Many instruments were designed for paper/pencil, but there is a growing interest in whether or not they can be

administered electronically.[65] PRMs often do not need to be completely redeveloped for electronic administration, but additional testing for equivalence should be conducted, leading to some instrument modification.[65] The types of changes needed range from relatively minor to extensive. Examples of small changes include things like updates to instructions and formatting. Examples of moderate changes include things like updates to item wording. Examples of significant changes include serious changes to item wording or response options. When tested, there often turns out to be little difference between electronic and paper and pencil versions of instruments. Gwaltney and colleagues performed a meta-analysis of RCTs testing the differences between these modes of administration among PRMs.[66] Among 46 studies, they found that mean difference in scores between electronically and paper-and-pencil administered instruments was, on average, 0.2%, and the average weighted correlation between scores, including multiple types of correlation coefficient and weighted kappa, was 0.90 (95% CI: 0.87-0.94). Additionally, regarding PROMIS measures specifically, a cross-over design RCT was used to compare mode of administration on item responses for physical function, fatigue, and depression scales, and found no differences in responses when administered on an interactive voice response system, paper-and-pencil response, and electronic survey approaches, including on computers.[67] **These results are encouraging, and similar efforts should be made for key PRMs used in dialysis to determine if any modifications are needed before electronic administration is advised.**

In addition to the mode of administration, there are differences in the mode of survey dissemination that are important to consider, and may have an impact on the success of the survey. Anastario and colleagues compared protocols for the distribution of the CAHPS clinician and group surveys.[68] In comparison to a mail-based dissemination protocol, a hand-out protocol had a sub-optimal distribution rate (74%) and a lower response rate (40% vs 58%).

The appropriate timing of PRM administration in clinic depends on the purpose of the assessments. In the context of clinical trials, the FDA's Center for Drug Evaluation and Research identified the following possible assessment approaches: at the beginning and end of a particular treatment, at or after important medical events occur (e.g., starting a new type of dialysis, development of a clinically significant comorbidity), or at regular, repeated intervals to examine progress of a chronic condition.[69,70] Though all of these approaches may be relevant to PRM assessment as part of standard clinical care in dialysis, long term monitoring over repeated intervals may be most relevant. For instance, a HRQOL measure may be assessed when a patient begins dialysis then administered at regular intervals thereafter to track potential improving or worsening health.

Indeed, the most benefit may be realized from administering PRMs at multiple occasions with patients.[71] Multiple administrations allow clinicians to track changes over time to monitor disease progression or to examine responses to changes in treatments. Despite this benefit, most often, PRMs are only administered once to patients.[71] This concurs within the field of dialysis as well. Although CMS has mandated the assessment of HRQOL and patient experience, these PRMs are most often assessed only once or twice for each patient. While single timepoint assessments are certainly superior to no PRM assessment at all, repeated assessments drastically increase the capacity to understand patients' health and experiences with dialysis so that adjustments in care can be made. The value of longitudinal assessment of PRMs has been raised specifically in regards to the CAHPS measures.[72] CAHPS items ask about experiences with care over the previous 6 months; if repeated every 6 months, experiences with care occurring over specific durations of time can be isolated, and the reports generated can be easily used for quality improvement if necessary. Other approaches, wherein all care received in the past is asked about,

do not offer the opportunity for longitudinal assessment, since repeated assessments of such measures would yield uninterpretable information due to the inability to pinpoint which specific durations of care were being described by the reports.[73]

There are a few challenges to longitudinal assessment of PRMs. First, repeated measures on the same patient over time may entail a lack of timely reports of results to providers. Second, due to frequent patient turnover in some clinics, longitudinal measurement may not be possible for all patients, creating a potential challenge to standardized longitudinal measurement for all patients. Finally, many of the barriers to cross-sectional PRM measurement may be compounded with repeated measurement, including increased costs, provider burden, and patient burden. **Considering both the benefits and burdens of repeated PRM measurement, we recommend that key PRMs be assessed twice annually for each patient so that some change can be observed in response to changes in treatment plans.** The CMS requirements for the ICH-CAHPS already adhere to this recommendation, though we suggest that the KDQOL-36 assessment recommendations be altered so that it is also assessed twice annually.

VI. Challenges

Though there are many clear benefits to administering PRMs in dialysis centers, there are also challenges. First, though we noted in the previous section the significant benefits to assessing PRMs over multiple timepoints, doing so can be burdensome for dialysis providers and dialysis patients. There is evidence that dialysis providers often have an extensive workload, and adding of PRMs adds to this workload.[74] A related practical challenge regards the additional cost associated with administering PRMs in the dialysis clinic. The staff time and resources, as well as material costs, required to administer a PRM, along with entering the data, then interpreting the results and incorporating the learning into clinical practice is not free, and may be difficult to

justify in clinics without significant discretionary spending.[1] **We recommend that new explorations be launched to identify mechanisms for CMS to reimburse these costs**.

Another important barrier regards staff training to administer key PRMs[1]. When PRMs are administered in an interview style from the dialysis staff, they require understanding of standardized survey administration techniques, including ways to elicit unbiased, accurate responses and trouble shoot when patients have questions, understand potentially complex skip-patterns, and screen for patient responses that may be untruthful or not genuine (e.g., a patient gives several of the same responses consecutively quickly in order to complete the assessment). Even when PRMs are administered through self-administered surveys (e.g., mailed to the patients), data entry protocols to reduce error are recommended, and these require training. **Therefore, the continued development of effective, low-cost training programs to help providers administer PRMs, including e-learning programs, should be a top priority.**

Additionally, patients' willingness or ability to participate in surveys of PRMs represents a potential barrier. Response rates to such surveys vary considerably and by the mode of administration. For example, in a randomized study of response rates to PRM-based surveys among 2,400 hip-replacement patients in Sweden, Rolfson and colleagues found a 92% response rate for paper surveys disseminated by mail vs. a 49% response rate for internet-based survey ($p<0.001$) .[75] In a larger study of 131,447 knee, hip, hernia, or varicose vein surgery patients in England, response rates to a post-surgical mail survey ranged between 65% (varicose vein surgery) to 85% (hip surgery) .[76]

Though the most significant contribution of PRMs is that they represent the patient's perspective, patient reports may generate biased and inaccurate data. Patients may give inaccurate responses in interview-based surveys in which they are speaking directly to a care

provider, either in the clinic or over the phone.[17] This may be because of social desirability or wanting to please the provider by reporting that their health is good or that they have had good experiences with care. Relatedly, patients may not trust providers enough to divulge sensitive information. A particularly apt example involves reports of patients' satisfaction with care when reported directly to the providers of that care. In this circumstance, patients who feel unsatisfied with their care may not feel comfortable to report this to providers. An additional source of bias for PRMs is recall bias, wherein patients may not have sufficient memory of the events or health states they are asked about to provide accurate responses.[77] One review found that recall bias was particularly high for reporting on HRQOL (e.g., health transition) and pain intensity.[78] Another important issue with administering PRMs in clinic regards the potential for response burden. Some patients, especially ones who are very sick, may feel burdened by completing extensive surveys or interviews. These issues and other can have a significant impact on the quality of the data from PRMs administered in dialysis centers.

Finally, the PRMs themselves can create barriers to clinical implementation. PRMs without established guidelines for clinically or minimally important differences (e.g., for change in health status) may be difficult to interpret. Similarly, measures without established population and case-mix adjusted norms for comparison may be less meaningful to discuss with patients since it cannot be easily determined how any one patient compares to average dialysis patients, or to other dialysis patients with similar demographic and clinical characteristics. PRMs that are used with individuals in clinic must have high reliability, 0.90 or higher.[79] Achieving such high reliability requires including many items in PRMs, which itself can increase response burden for patients. Therefore, it is important to select measures that balance brevity and high reliability,

though trade-offs in one, if not both, of these areas may be required in choosing a measure that is feasible to implement in dialysis centers.

VII. Recommendations

The philosophy underlying PRMs is that patients have critical information about their own health that should be included in creating treatment plans. In choosing PRMs to administer in dialysis clinics, the top priority should be on collecting information that elicits patients' perspectives and preferences for their health and use of healthcare, and that can lead to improvements in these domains through clinical interventions. In selecting measures, the psychometric properties should be considered, and measures with extensive support for their reliability and validity should be given priority. When the goal is to use the measure for individual assessment and intervention, it is critical that measures with high reliability be selected.

As performance monitoring and incentives for quality improvement expand within the field of dialysis, and PRMs play a potentially larger role in this enterprise, it is important to recognize the benefits that may result and how PRMs can improve dialysis care. CMS is already incentivizing the use of PRMs in dialysis, which rewards centers that invest more in patient-centered care in their QIP program. Another way CMS leverages the results of PRMs to impact care is by publishing the results of patients' reports of their health and ratings of experiences of care and allowing patients to choose providers based on these results.[1] In this way, the patient's voice can define high- versus low-quality care, and chart a path toward truly patient-oriented dialysis. Dialysis providers should embrace this trend. Increasing the patient's voice in the provision of dialysis will not supplant or replace the provider's, but will provide critical feedback on ways that providers can monitor the impact of dialysis and make changes where necessary.[80]

To date, little to no data on the impacts of assessing HRQOL and patient experience in the QIP process is available. This is an area of the highest importance in ongoing research.

Although some research on the provision of PRMs in medical care in general, and in dialysis specifically, has emerged, there are many areas requiring further exploration. First, more research should be conducted to determine the most efficient and successful modes of administering PRMs among dialysis patients. This should take the form of a randomized trial comparing response rates and completeness of responses between different modes of administration and delivery like paper in-clinic versus electronic surveys in patients' homes. Additionally, though large-scale investigations of the impact of administration of PRMs in clinic have been generated for other types of treatment, such evaluations, also randomized, are needed within dialysis.

In addition to these general recommendations, we summarize the major, specific recommendations generated throughout the sections above are summarized here in Table 4.

Table 4. Specific Recommendations for Continued Use of PRMs in Dialysis Centers

Category	Recommendations
Selection of PRMs	❖ Continue the use of KDQOL-36 for dialysis centers' internal quality improvement activities and the ICH-CAHPS for public dialysis center performance monitoring, but promote efforts to modify these instruments by incorporating PROMIS general health items (KDQOL-36) and reducing the length of the ICH-CAHPS. ❖ Adopt a PRM of whether dialysis patients have been informed about their option for transplant.
Mode of Administration	❖ Evaluate equivalence between electronic and paper versions of PRMs prior to widespread use of electronic administration.
Support for PRM Use	❖ Explore reimbursement of costs of PRM administration by the Centers for Medicare and Medicaid Services. ❖ Continue development of provider trainings in PRM administration and interpretation.

VIII. Conclusions

In conclusion, there is a lot to celebrate in the field of PRMs in dialysis. Many strong measures have been developed and validated, and their use in dialysis centers is extensive. Despite these successes, there is significant room for improvement. We have identified several pointed recommendations for improving the use of PRMs in dialysis. These recommendations are intended to help dialysis care decision-makers, clinicians, and applied researchers continue to improve the excellent track record of PRM use in dialysis.

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